**PATENT** 

Attorney Docket No.: JHU1800-3

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Lee et al.

Art Unit:

1645

Application No.:

10/665,374

Examiner:

Not Yet Assigned

Filing Date:

September 16, 2003

Confirmation No.:

5508

Title:

METALLOPROTEASE ACTIVATION OF MYOSTATIN, AND

METHODS OF MODULATING MYOSTATIN ACTIVITY

MAIL STOP 1645 Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.97, enclosed are references relating to the above-identified application. For the convenience of the Examiner, the references are listed on the attached Form PTO-1449 and a copy of each reference is enclosed herewith.

It is respectfully requested that the references be considered in the examination of this application and their consideration be made of written record in the application file.

### CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service with sufficient postage as first class mail on this date, April 26, 2004, in an envelope addressed to: MAIL STOP 1645, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Gregory P. Austin

(Name of Person Mailing Paper)

Signatural P. Gusto

April 26, 2004

(Date)

In re Application of:

Lee et al.

Application No.: 10/665,374 Filed: September 16, 2003

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PATENT Attorney Docket No.: JHU1800-3

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement, because it is being filed prior to the mailing of a first office action on the merits of the

above-identified application. However, if any fee is required, authorization is hereby given to

charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: April 26, 2004

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# TRANSMITTAL LETTER

Sir:

Transmitted herewith for the above-identified application please find:

- 1. Information Disclosure Statement (2 pgs.);
- 2. Form PTO-1449 (2 pgs. in duplicate);
- 3. Seventeen (17) References; and
- 4. Return Receipt Postcard.

#### **CERTIFICATION UNDER 37 CFR §1.8**

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service with sufficient postage as first class mail on this date, April 26, 2004, in an envelope addressed to: MAIL STOP 1645, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Gregory P. Austin

(Name of Person Mailing Paper)

Gregor P. austri

April 26, 200

(Date)

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No.: JHU1800-3	Application No.: 10/665,374
APR 2 9 2004	Applicants: Lee et al.	Confirmation No.: 5508
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: September 16, 2003	Group Art Unit: 1645

# **U.S. PATENT DOCUMENTS**

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA	2003/0104406 A1	06/05/2003	Wolfman et al.	435	6	02/08/2002

# **FOREIGN PATENT DOCUMENTS**

EXAM. INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
						-

# OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

AB	Blader et al., "Cleavage of the BMP-4 antagonist chordin by zebrafish tolloid", <i>Science</i> , 278(5345):1937-1940 (Dec. 1997)
AC	Bogdanovich et al., "Functional improvement of dystrophic muscle by myostatin blockade", <i>Nature</i> , 420(6914):418-421 (Nov. 2002)
AD	Hill et al., "Regulation of myostatin in vivo by growth and differentiation factor-associated serum protein-1: a novel protein with protease inhibitor and follistatin domains", <i>Mol. Endocrinol.</i> , 17(6):1144-1154 (June 2003)
AE	Hill et al., "The myostatin propeptide and the follistatin-related gene are inhibitory binding proteins of myostatin in normal serum", <i>J. Biol. Chem.</i> , 277(43):40735-40741 (Oct. 2002)
AF	Kessler et al., "Bone morphogenetic protein-1: the type I procollagen C-proteinase", Science, 271(5247):360-362 (Jan. 1996)
AG	Lee et al., "Regulation of myostatin activity and muscle growth", <i>Proc. Natl. Acad. Sci. USA</i> , 98(16):9306-9311 (July 2001)

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No.: JHU1800-3	Application No.: 10/665,374
	Applicants: Lee et al.	Confirmation No.: 5508
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: September 16, 2003	Group Art Unit: 1645

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АН	Li et al., "The C-proteinase that processes procollagens to fibrillar collagens is identical to the protein previously identified as bone morphogenic protein-1", <i>Proc. Natl. Acad. Sci. USA</i> , 93(10):5127-5130 (May 1996)
AI	Marques et al., "Production of a DPP activity gradient in the early Drosophila embryo through the opposing actions of the SOG and TLD proteins", Cell, 91(3):417-426 (Oct. 1997)
AJ	McPherron et al., "Double muscling in cattle due to mutations in the myostatin gene", Proc. Natl. Acad. Sci. USA, 94(23):12457-12461 (Nov. 1997)
AK	McPherron et al., "Regulation of skeletal muscle mass in mice by a new TGF-beta superfamily member", <i>Nature</i> , 387(6628):83-90 (May 1997)
AL	Piccolo et al., "Cleavage of Chordin by Xolloid metalloprotease suggests a role for proteolytic processing in the regulation of Spemann organizer activity", <i>Cell</i> , 91(3):407-416 (Oct. 1997)
AM	Takahara et al., "Bone morphogenetic protein-1 and a mammalian tolloid homologue (mTld) are encoded by alternatively spliced transcripts which are differentially expressed in some tissues", J. Biol. Chem., 269(51):32572-32578 (Dec. 1994)
AN	Takahara et al., "Characterization of a novel gene product (mammalian tolloid-like) with high sequence similarity to mammalian tolloid/bone morphogenetic protein-1", <i>Genomics</i> , 34(2):157-165 (June 1996)
AO	Uzel et al., "Multiple bone morphogenetic protein 1-related mammalian metalloproteinases process pro-lysyl oxidase at the correct physiological site and control lysyl oxidase activation in mouse embryo fibroblast cultures", <i>J. Biol. Chem.</i> , 276(25):22537-22543 (June 2001)
AP	Wolfman et al., "Activation of latent myostatin by the BMP-1/tolloid family of metalloproteinases", <i>Proc. Natl. Acad. Sci. USA</i> , 100(26):15842-15846 (Dec. 2003)
AQ	Wozney et al., "Novel regulators of bone formation: molecular clones and activities", <i>Science</i> , 242(4885):1528-1534 (Dec. 1988)

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